

**CREDENTIALING OF PERSONNEL
IN RESEARCH & DEVELOPMENT SERVICE**

1. PURPOSE: To establish a Research & Development (R&D) Service level policy that identifies personnel involved in human, animal and laboratory research and a compliance system for the credentialing of such personnel.

2. POLICY:

a. All research personnel must submit an Education Verification form and a Scope of Work (SoW) form signed by the principal investigator of research in which they may be involved in (if different from the supervisor), to the Research Administration Office. For human research, the SoW form will be specific to each person for each approved protocol. For lab/animal research, the SoW form will be specific to each PI for whom an individual works.

b. All research personnel involved in human research must be credentialed. The Research Administration Office is responsible for determining which individuals require credentialing in the web-based Federal Credentialing Program for Healthcare Providers (VetPro) based on the completed Education Verification form. Those requiring VetPro credentialing include all who have a health care license, certification or registration (e.g., medical license, nursing license, American Speech-Language-Hearing Association (ASHA) certification EMT, MRI Technician), OR training that offers the potential for such licensure or certification OR a degree offering the potential for such licensure or certification (e.g., MD, BSN, MSW, Medical Technician, LPN, BS Pharmacy, etc.). Such credentialing will add assurance that personnel are appropriately educated, certified, and/or hold a health care license to effectively and safely perform Portland VA Medical Center (PVAMC) approved human research at the PVAMC. The policy will also assist in assuring only those with appropriate credentials will be involved with PVAMC approved human research. **Exception** to the requirement for VetPro: Residents/fellows/clinical trainees must be verified via a Resident Credentials Verification Letter (RCVL) from the Medical Professional Service Office, or in the case of trainees in Mental Health, a Trainee Qualifications and Credentials Verification Letter (TQCVL) from the Education Office. Any resident/fellow/trainee from Oregon Health Science University (OHSU) who will not have a clinical rotation and will only work on VA research at PVAMC and therefore does not have an RCVL or TQCVL on file at PVAMC, must be credentialed in VetPro.

3. RESPONSIBILITIES:

a. The **Associate or Deputy Associate Chief of Staff for Research & Development (ACOS/R)** is responsible for:

- (1) Completing credentialing requirements, as defined by national and local policy
- (2) Completing the SoW form unless this is not required per national and local policy.

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- (3) Developing and managing credentialing policies and procedures for personnel involved in human, animal and laboratory research.
- (4) Ensuring that all PVAMC research personnel involved in human research have completed the appropriate credentialing requirements consistent with VA policy.
- (5) Reviewing, approving and signing each SoW form.
- (6) Conducting an annual quality assurance review of SoW forms for R&D Service personnel and reporting those findings to the R&D Committee.

b. The **Administrative Officer for Research & Development (AO/R)** is responsible for:

- (1) Completing credentialing requirements as defined by national and local policy
- (2) Completing the SoW form unless this is not required per national and local policy.
- (3) Overseeing the Research Administration Office staff involved with the process of credentialing personnel involved in human research.
- (4) Working with Human Resources to ensure without compensation (WOC) appointments are completed when appropriate.
- (5) Overseeing the Research Administration Office staff involved with initial review of SoW.
- (6) Maintaining SoW of Work files for all research personnel.

c. **All Research staff** are responsible for completing credentialing requirements as appropriate and completing the SoW form unless either of these is not required per national policy.

d. **Research Administration Office Staff Member(s)** (designated by AO/R) is responsible for:

- (1) Identifying and requesting the credentialing of PVAMC human research personnel who have health care licensure/registration/certification or the potential for such as appropriate.
- (2) Requesting VetPro credentialing through Medical Professional Service, Nursing Professional Service or Human Resources as appropriate and documenting the VetPro appointment and expiration date in the appropriate research database.
- (3) Assuring a RCVL or TQCVL, if applicable, is on file and recording the expiration date in the Research Personnel Database.
- (4) Monitoring personnel compliance with the credentialing requirements.
- (5) Reviewing all SoW forms, submitting SoW forms to the ACOS/R for signature, and consulting with the ACOS/R if any questions about qualifications for any procedures.
- (6) Informing the AO/R and ACOS/R of areas of non-compliance with credentialing requirements.
- (7) Maintaining the SoW and Credentialing section of the appropriate research database.

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(8) On a monthly basis, assuring all research appointees in human research are not the subject of regulatory action, and have completed all credentialing requirements.

(9) Maintaining documentation of SoW and Education Verification for all personnel working in human research.

4. PROCEDURES:**a. Definitions:**

(1) **Credentialing:** Systematic process of screening and evaluating qualifications and other credentials, including licensure, education, training, and experience, and current competence and health status.

(2) **Federal Credentialing Program for Healthcare Providers (VetPro):** VetPro is an Internet enabled data bank for the credentialing of VHA personnel that facilitates completion of a uniform, accurate, complete credentials file.

(3) **Research Personnel** includes, but not limited to, PVAMC paid employees (Title 5, Title 38 and Title 38 Hybrid), Portland VA Research Foundation (PVARF) employees, Oregon Health & Science University (OHSU) employees, other without compensation (WOC) appointments, residents, trainees, fellows, fee basis, consulting and attending, etc.

(4) **Resident Credentials Verification Letter (RCVL):** A document signed by the program director of an affiliate medical school, or VA program director must verify all credentials of residents and trainees and sign the RCVL. A new RCVL is required for each academic year appointed, before approval of appointment is granted by the Medical Center Director.

(5) **Scope of Work (SoW):** A written document that defines the parameters and functions of an employee's duties and responsibilities. These duties and responsibilities must be consistent with the occupational category under which they are hired (appointment by Human Resources (HR) to the position) allowed by the license, registration, or certification they hold, consistent with their qualifications (education and training), and be agreed upon by the person's immediate supervisor and the ACOS/R. When the employee is working on specific research protocols, the PI for each protocol must also agree with the Scope of Work statement.

(6) **Trainee Qualifications and Credentials Verification Letter (TQCVL):** A document that contains student information completed by an affiliate medical school that documents that the student is in good standing, has a current Basic Life Support (BLS) card, has the required immunizations, and has reviewed the required PVAMC Computerized Patient Record System (CPRS) training PowerPoint prior to the clinical experience.

b. Research personnel must obtain either a VA-paid or WOC appointment if they:

- Work on PVAMC property;
- Interact with PVAMC research participants via telephone or in-person except as listed in item c.(1) below;

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- Collect and analyze identifiable patient laboratory specimens or patient data of participants in a PVAMC approved study;
- Perform patient laboratory tests or work with identifiable patient data of participants in PVAMC research studies;
- Work in the R&D Office, i.e. ACOS/R, Deputy ACOS/R, AO/R, R&D Committee Coordinator, IRB Analysts, IACUC Coordinator, Subcommittee on Research Safety Coordinator, Grants Administrators, Research Assurance Officer (RAO), R&D Service Staff; or
- Serve as R&D Committee and/or IRB members.

Information is available on the R&D Service Web site at:

<http://www.portland.va.gov/research/piservices/hiring/appointmentrequirements.asp>.

c. Personnel involved in PVAMC IRB-approved human research projects who meet the following criteria are NOT required to complete the credentialing requirements:

- (1) Members of the research team who are strictly administrative staff, e.g., receptionist or any individuals that may have contact with a patient for scheduling purposes only.
- (2) Members of the research team, e.g., biostatisticians or lab technicians who do not come to the PVAMC and do not directly interact with VA research participants or see their identifiable specimens or data.
- (3) Volunteers from the community who serve on an IRB or R&D Committee and members of groups such as Data Safety Monitoring Boards (DSMBs) who are recruited from non-VA institutions.

d. Individuals who do not meet the criteria above in item c. and are applying for either VA-paid or research WOC appointment (unpaid volunteer or paid by PVARF, OHSU, or some other outside entity) must submit the following to the Research Administration Office (see R&D Service Web site at:

<http://www.portland.va.gov/research/piservices/hiring/appointmentrequirements.asp>):

- (1) The applicable checklist (see <http://www.portland.va.gov/research/piservices/hiring/appointmentrequirements.asp#checklists>);
- (2) All applicable forms available at: <http://www.portland.va.gov/research/piservices/hiring/appointmentrequirements.asp#forms>.

e. Research Administration Office staff designated by the AO/R will:

- (1) Review SoW forms, follow-up concerning any questionable procedures, and obtain ACOS/R signature.
- (2) For those with a health care license, certification or registration, or the potential for licensure, certification or registration, assure VetPro has been completed, and if necessary, submit a request for VetPro credentialing to Medical Professional Services or Nursing Professional Services, as applicable.

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(3) For medical residents/fellows/trainees, assure a current RCVL/TQCVL is on file.

(4) Maintain credentialing files for all individuals working on PVAMC approved research and/or who require VetPro credentialing.

(5) Notify the AO/R and ACOS/R or Deputy ACOS/R immediately in the event an individual appears on any exclusionary list or is found to have an expired license. Appropriate action will be taken with consultation from HR. The following will be checked monthly:

- The FDA Debarment List and FDA Disqualified/Restricted/Assurance List for Clinical Investigators on the FDA website.
- The Public Health Service Administrative Actions Listing.
- The Research Personnel Database for expired VetPro appointments and residency/fellowships.

f. **Record Retention:** Credentialing files will be maintained for a minimum of six years after the termination date of an individual's appointment and/or indefinitely in accordance with current records retention requirements.

5. REFERENCES:

a. VHA Directive 1200.

(http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=2043)

b. VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research.

(http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=2531)

6. CONCURRENCES: Endorsed by the Research & Development Committee on 04/07/2014.

7. RESCISSION: HRPP: P&P No. 10, Endorsed by the Research & Development Committee on 01/26/2004, 04/04/2005, 08/01/2005, 04/6/2009, 08/30/2010 and 02/07/2012.

8. FOLLOW-UP RESPONSIBILITY: ACOS, Research & Development Service

Michael P. Davey, M.D., Ph.D.
ACOS, Research & Development Service